REMARKS

In the Office Action dated May 9, 2002 the Examiner has preserved in the requirement for restriction and further rejected the elected claims for grounds under Section 112. Based on this response, reconsideration of the merits of this patent application is respectfully requested.

The sole issue with regard to the patentability of Claims 2-3 and 5-6 is a rejection under 112, second paragraph, for indefiniteness. The Examiner contends that the claims are incomplete for omitting essential steps. The applicants believe that no essential steps are omitted, and the applicants continue to contest this rejection.

In the applicants' view, part of the resolution of this question depends on the answer to the Examiner's question expressed in the Office Action as follows: "If everything is known and well within the purview of one of ordinary skill in the art, they why should applicants be entitled to patent eligibility?" The applicants feel they have an answer to that question. The applicants are the first to have identified the fact that the adenovirus type 36p is strongly associated with obesity and is the cause of virally induced obesity. It is this observation, and its implementation in clinical testing, that entitle the applicants to a patent. This observation is unobvious and novel to the art. The fact that it is unobvious is reflected by the fact that no prior art rejection is made against the claims of this application.

It is the applicants' assertion that once science has determined that a virus is important to detect in a subject, there are any number of methodologies which can be used to detect that virus. Specifically, for example, the creation of an antibody to an epitope on a virus is no longer unobvious and is well within the ambit of one of ordinary skill in the art. If the applicants had presented a claim which read, in essence, an antibody to an epitope on adenovirus type 36p, the Examiner would probably reject the claim for obviousness, since the virus is itself old. What the applicants have demonstrated here is that there is now a reason to detect this virus, which previously had no associated health effect and no particular clinical significance. The particular antibody which is used to detect the virus, and the particular form of the immunological test to detect the virus, are not critical to this invention. There are many alternatives known in the world on methods and reagents for antibody-based testing. One can use sandwich ELISA's, simple ELISA's, one can use captive antibodies, and one can detect antibody antigen interaction using fluorescent techniques or radiological techniques, or even direct electrical techniques. These techniques are well known in the art and well

illustrated in the patent literature. Since it is not particularly critical which method is chosen to perform the method here, it is not particularly important which of those techniques are actually utilized in detecting the presence of the virus in a test sample from a subject. The claims are simply not incomplete on this point.

It is a fundamental principal of patent law that the claims should be commensurate with the scope of what the applicants have enabled. The applicants here have demonstrated, for the first time, that this particular virus is associated with viral induced obesity. The claims have a breadth commensurate with that contribution to the knowledge of mankind. Why should the applicants be forced to amend their claims to recite a particular immunological technique to detect the virus, when many are known to those of skill in the art?

There are two broad techniques described in the patent specification and claimed in this application for detecting this virus. One is to use an immunological technique, i.e., a technique based on an antibody which recognizes an epitope on the virus. The other is to do a nucleic acid detection technique to identify an RNA or DNA species indicative of the presence of the virus. As with immunological techniques, there are any number of nucleic acid techniques that can be used to detect the virus. Obviously the most common that is in use today is PCR, and all that is required to perform PCR for one of ordinary skill in the art is DNA indicative of the presence of the virus. The applicants have supplied the DNA indicative of the virus of which it is aware, but it is also well within the ambit of ordinary skill in the art to continue sequencing of the virus and find other sequences diagnostic of this virus. In addition to PCR, there are any number of DNA hybridization techniques which can be used to detect DNA in a sample. One can use DNA microarrays to detect nucleic acids in a sample. One can use radiological hybridization techniques to detect DNA in a sample. One can perform DNA sequencing techniques on DNA found in samples. The selection of the particular nucleic acid detection technique, and the method by which it is performed, is again not critical to the method described herein. What is important here is that the adenovirus type 36p virus is detected. The fact that the virus is important to be detected is what the applicants have demonstrated and contributed to the knowledge in the art. The claim granted to them should be of commensurate scope.

Wherefore the Examiner is respectfully once again to revisit the merits of this patent application. A separate petition for extension of time is submitted herewith so that this response will be considered as timely filed.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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Title: VIRAL OBESITY METHODS AND COMPOSITIONS

Our Ref: 710395.90010

2. (Twice Amended) A method of determining whether an obese person is suffering from viral obesity caused by adenovirus type 36p, the method comprising the steps of isolating from the person a sample selected from the group consisting of a body fluid, feces, a sample of tissue and a sample of an organ from the person and; assaying the sample by an immunoanalytical [or nucleic acid probe hybridization] method to test for the presence of an epitope of the adenovirus type 36p thus testing whether the person has been or is infected with adenovirus type 36p, which causes obesity and reduces cholesterol level in humans.

3. The method according to Claim 2 wherein the substance analyzed is blood. ? L.A.B.

5. (Amended) A method for the detection of virally caused obesity in an obese subject comprising the steps of

isolating a nucleic acid from the body of the subject; [and]

[assaying] testing the isolated nucleic for the presence of nucleic acid sequences from adenovirus type 36p; and

detecting the presence of said sequences wherein the detection indicates the presence of viral induced obesity in the subject.

6. (Amended) A method for the detection of virally caused obesity in an obese subject comprising the steps of

isolating a sample of biological tissue or fluid from the subject; [and]

[assaying] testing the sample, using an immunological probe [for] diagnostic for adenovirus 36p; and

detecting the presence of adenovirus type 36p to determine if the subject has viral induced obesity.

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